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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,221	12/11/2000	Dan R. Littman	1049-1-004n2	6077
7590 12/20/2005 Klauber & Jackson 411 Hackensack Avenue Hackensack, NJ 07601			EXAMINER LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No. 09/734,221	Applicant(s) LITTMAN ET AL.	
Examiner Bao Qun Li	Art Unit 1648	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 17 October 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 7, 37 and 74.  
Claim(s) withdrawn from consideration: 1-26, 33-36, 38-40 and 61-73.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached office action.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☒ Other: Interview summary.

Art Unit: 1648

### ADVISORY ACTION

The response to the final action filed on October 20, 2005 under 37 CFR 1.116 has been entered. However, the amendment of the claims has been considered but is not deemed to place the application in condition for allowance.

For purpose of appeal, the status of the claims is as follows:

**Pending claims: 1-26, 33-40, 61-74.**

**Allowed claim(s): NONE.**

**Rejected claim (s): 37, 70 and 74.**

**Claim(s) objected to: NONE.**

**Claims withdrawn from consideration: 1-26, 33-36, 38-40, 61-69 and 71-73**

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 37, 70 and 74 are still rejected under 35 U.S.C. 112, first paragraph under the same ground as stated in the previous Office Action, because the specification, while being enabled for having a method of screening an HIV-1 macrophage tropic (HIV M-tropic) fusion inhibitor with cells expressing both CD4 and CCR5 in the presence of M-tropic HIV-1 infection or a virus pseudotyped with a full-length of HIV M-tropic envelope protein, wherein the inhibitor can be used for treating a patient infected with a M-tropic HIV virus sensitive to the said inhibitor, does not reasonably provide enablement for a method of screening any or all HIV fusion inhibitor with a cell that only expresses CCR5 in the presence of any virus pseudotyped with any or all kind of M-tropic envelope, wherein an inhibitor identified by the method can be used for prevention of AIDS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Art Unit: 1648

3. Applicants traverse the rejection and submitted that claim 37 have amended as a method of identifying an agent that inhibits an HIV infection caused by a macrophage-tropic virus whose entry into cells is mediated by CCR5. Therefore applicants assert that the rejection should be withdrawn. Applicants' amendment as well as argument has been respectfully considered; however, it is not persuasive because this amendment does not overcome the rejection in that the scope of method reads on identifying agent with a virus pseudotyped with any kind of Macrophage-tropic envelope protein. The state of art does not teach that any macrophage-tropic envelope protein can bind to CCR5 and induce fusion pointed out in the previous office action (page 9, paragraph 19) mailed on December 21, 2004, The specification does not provide sufficient evidence to support this scope of claims and the state of art does not teaches that every envelope protein for any macrophage-tropic virus can fuse with the target cell via CCR5. The rejection is therefore, maintained.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claim 37 is still rejected under 35 U.S.C. 102(a) as being anticipated by Cocchi et al. (Science 1995, Vol. 270, pp. 1811-1815) in light of Moriuchi et al. (J. Immunol. 1997, Vol. 159, pp. 5441-5449) on the same ground as stated in the previous Office Action.

6. Applicants traverse the rejection and submit that the patent law is settled that a rejection under 35 U.S.C. 9102 is proper only if a single reference discloses every single element of an invention as claimed. The patent law is also clear that in certain circumstances a reference need not expressly disclose every single element of an invention as claimed if the element is inherent in the disclosure of the prior art reference. However, the patent law is equally clear that certain conditions must be met before an element may be found to be inherent in the disclosure of a prior art reference. Applicants admitted that the Examiner correctly outlines these conditions as settled by the Federal Circuit citing the review article of Feit et al. (2003, J. Pat. Trade Off. Soc., Vol.

Art Unit: 1648

85, No. 1, pages 5-21) when the examiner use the prior art by Cocchi et al. to reject the claims. However, Applicants still argue that 1). Cocchi et al. do not teach or suggest all of the limitations of claim 37 as currently amended, either expressly or inherently, i.e. Cocchi et al. do not teach or suggest a method of selecting an agent for possible use in the treatment of the HIV-1 infection caused by a macrophage-tropic HIV virus, wherein the entry for the macrophage-tropic virus into the target cells is mediated by CCR5; 2). Cocchi et al. do not teach or suggest that chemokines such as RANTES, MIP-I alpha or MIP-I beta prevent the virus from fusing with the cells mediated by CCR5 recited in the currently amended claims; 3). The CCR5 is a co-factor for the Monocyte tropic HIV was not known at the time when Cocchi et al. reference was published.

7. Applicants' argument has been respectfully considered; however, it is not found persuasive because the rebottle of this argument has been clearly discussed in the previous office actions. The inherency rejection is based on that the reference by Cocchi et al. teach method uses same type of cell inherently expresses CCR5, same virus, and an reagent for testing if the reagent (recombinant chemokines) can inhibit the monotropic HIV infection. The inherency is that the CCR5 is inherently expressed by the testing target cells used in the assay, and it is the co-factor mediated M-tropic HIV envelope protein fused with the target cell inherently via CCR5 expressed on the surface of said target cells and the inhibition by the testing chemokine is inherently via blocking the fusion mediated by the CCR5 even though CCR5 is discovered as the co-factor for the fusion of macrophage-tropic HIV-2 envelope protein to the target cell. Therefore, the prior art teaches each and every limitation of the claimed method. Regard to argument that time of identifying CCR5 as M-tropic HIV fusion-cofactor later than the publication by Cocchi et al., Feit et al. indicate that it is irrelevant whether it was apparently at the time of filling the application in question. Therefore, the rejection is remained.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

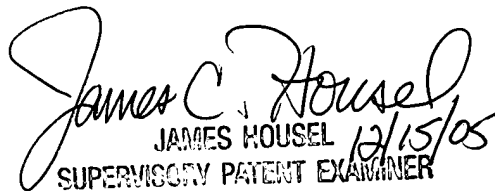
Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

12/15/2005

  
JAMES HOUSEL 12/15/05  
SUPERVISORY PATENT EXAMINER  
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